

This objection is respectfully traversed and Applicant respectfully requests reconsideration in view of the following remarks:

The Applicant notes that the Examiner acknowledges a difference between claims 22 to 36 of the instant application and claims 1 to 7 of U.S. Patent No. 6,451,122, namely, a water content greater than 1%.

Indeed, the dextrose in powder form claimed in U.S. Patent 6,451,122 has a water content of at most 1% and is therefore called anhydrous whereas the dextrose in powder form of the invention has a water content greater than 1% and is called hydrated.

The dextrose hydrate in powder form of claims 22 to 36 of the instant invention is hence novel over U.S. Patent 6,451,122 and the statutory rejection for double patenting does not apply.

The dextrose hydrate in powder form of the instant invention further defines more than a mere obvious variation of the one claimed in U.S. Patent 6,451,122 for the following reasons:

In practice, the preparation of anhydrous dextrose in powder form is much more time and cost consuming than the preparation of dextrose hydrate in powder form. As a matter of fact, the removal of water from dextrose powder form requires a costly and time consuming drying step.

The invention claimed in U.S. Patent 6,451,122, was based on the Applicant's discovery that anhydrous dextrose in powder form according to the invention has exceptional properties of

compression and hardness. At the time of the invention the strong conditions of the drying step were seen as a prerequisite to obtain such properties of hardness and compression. It was hence believed at that time that only anhydrous dextrose in powder form would reach such hardness and compression properties.

The invention claimed in the instant application is based on the Applicant's surprising discovery that dextrose hydrate in powder form according to the invention shows even higher compression and hardness properties. This discovery goes entirely against all common expectations since at the time of the instant invention it was believed that only anhydrous dextrose in powder form could have high compression and hardness properties.

As a matter of fact, if it was so obvious that hydrate dextrose in powder form would show higher properties of hardness and compression, the Applicant would not have used such a costly drying step to obtain anhydrous dextrose in powder form in order to achieve the desired properties of compression and hardness.

The mere allegation that the prior art may be modified in an obvious manner to arrive at the invention does not make the modification obvious unless the prior art suggested the desirability of the modification (In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992); In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)).

The rejection for double patenting should hence be withdrawn.

Rejections under 35 U.S.C. 102(b) and 103(a)

Claims 22-36 were rejected under article 35 U.S.C. 102(b) or, in the alternative under article 35 U.S.C. 103(a) over Chase et al. (WO 94/28181).

This rejection is respectfully traversed and reconsideration is requested for the reasons that follow:

The Examiner acknowledges that the dextrose hydrate in powder form of the invention differs from the dextrose in powder form of Chase et al. as to the specific recitation of compressibility.

However, the Examiner is of the opinion that this specific compressibility is inherent to the dextrose in powder form of Chase et al.

The Examiner further states that the evidence provided with the declaration filed on September 30, 2002 is insufficient to overcome the rejection based upon Chase et al.

In support of his arguments and the declaration filed on September 30, 2002, Mr. Philippe LEFEVRE provides a new declaration along with a comparative showing which demonstrates that the dextrose in powder form of Chase et al. does not inherently possess the claimed specific compressibility values.

Please find this declaration and the comparative showing herewith enclosed.

This showing is a graphic which represents the compressibility, measured according to the test A described in

the application and in the declaration, on four tablets of dextrose hydrate in powder form according to the invention toward four tablets of the dextrose in powder form according to Chase et al..

As per test A, this compressibility is to be measured on tablets having a density of 1.3 g/ml. Mr. LEFEVRE hence performed measures of compressibility using test A on tablets having a density ranging from 1.195 g/ml to 1.445 g/ml, i.e. covering the value of 1.3 g/ml.

Four tablets were prepared with the dextrose hydrate in powder form of the invention, having respectively the following densities 1.195 g/ml, 1.273 g/ml, 1.287 g/ml and 1.324 g/ml. For these four tablets, a dextrose hydrate in powder form of the invention, having the following characteristics, was used:

- a dextrose content at least equal to 99%,
- an  $\alpha$  crystalline form content at least equal to 98%,
- and a water content of 7.6%.

Four tablets were prepared with dextrose in powder form prepared according to the process of Chase et al. having respectively a density of 1.296 g/ml, 1.399 g/ml, 1.420 g/ml and 1.445 g/ml.

Two curves of compressibility were drawn from the measures of compressibility of these eight tablets and are presented on the showing. The compressibility is represented, as is usual, by a curve in function of hardness (Y-coordinate) and density (X-coordinate).

As it can be seen on the showing, the curve of the dextrose hydrate in powder form of the invention lies far above the curve of the dextrose of Chase et al.. This means that the dextrose hydrate in powder form of the invention possesses a far higher compressibility than the dextrose in powder form of Chase et al.

The compressibility curve of the dextrose in powder form of Chase et al. lies under 60 N, whereas the compressibility curve of the dextrose hydrate in powder form of the invention lies above 93 N.

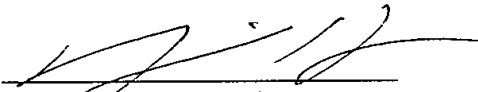
In particular, for tablets having a density of 1.3 g as required in test A, the compressibility of the dextrose hydrate in powder form of the invention is of 200 N, whereas the compressibility of the dextrose in powder form of Chase et al. is less than 25 N.

As a conclusion, and in support of his arguments and declaration filed on September 30, 2002, the Applicant believes that the showing and declaration enclosed provides sufficient comparative evidence, commensurate in scope with the claims, to overcome the rejection of claims 22-36 based upon Chase et al.

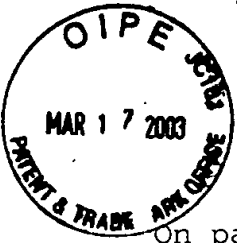
The rejection under article 35 U.S.C. 102(b) or, in the alternative under article 35 U.S.C 103(a) over Chase et al. (WO 94/28181) should hence be withdrawn.

Favorable consideration and prompt allowance of these claims are respectfully requested.

Respectfully submitted,  
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Version With Markings to Show Changes Made

On page 12, paragraph beginning at line 12:

More preferably, the dextrose selected is an  $\alpha$  crystalline dextrose having a water content at most equal to 1% in order to obtain a dextrose hydrate in powder form accoridng to the invention having, according to test A, a compressibility in the range 150 N to 200 N, and according to test B, a compressibility at least equal to 170 N and in particular in the range 175 N to [100] 300 N.

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